

REMARKS

Reconsideration of the present application is requested. Claims 54-65 and 69-72 had been previously allowed, while claims 34-40, 42-47, 49, 51-53 and 80-96 were rejected. In the present office action, the allowability of claims 54-65 and 69-72 has apparently been withdrawn. Although Applicants' prior arguments were deemed persuasive as to the previously rejected claims, a new rejection of all the pending claims has been lodged.

Now the claims have been rejected as anticipated by U.S. Patent No. 6,402,784 to Wardlaw. The pending claims include four independent claims 45, 54, 80 and 92. All of the independent claims refer to sealing an opening in the disc annulus while fluent material is introduced into the disc space – e.g., "sealably introducing under pressure" in claim 45, "a seal for cooperatively engaging the annulus fibrosus adjacent the opening" in claim 54, "said tube having a seal adapted to engage said annulus fibrosus adjacent said opening" in claim 80, and "providing a seal at the opening for sealing said opening" in claim 92. It was suggested that the device disclosed in Wardlaw includes a seal 16 for engaging the annulus and sealing the opening in the annulus. The element 16 in Wardlaw is a valve structure that is fluidly connected to the interior of an expandable cover 12 (col. 6, lines 35-41). The valve structure 16 includes a one-way valve 18 that restricts flow of fluent material "from the cover 12 through the valve structure 16". Col. 7, lines 18-30. Thus, the valve structure 16 in Wardlaw is only operable to seal the inflated cover, not the annulus fibrosus. The operation of the valve structure 16 to seal the cover does not require any interaction or engagement with the disc annulus.

Thus, Wardlaw cannot anticipate claim 54, which recites a seal "for cooperatively engaging the annulus fibrosus", claim 80, which recites a seal "adapted to engage said annulus fibrosus", or claim 92 which defines the step of providing a seal "for sealing said opening." Applicants have further amended claim 45 to make it clear that the step of "sealably introducing" the biomaterial requires sealably engaging the annulus fibrosus, which parallels the language in the other independent claims. Since the valve structure 16 in Wardlaw only seals internally (i.e., within the valve structure), and since this internal seal does not engage the disc annulus fibrosus, Wardlaw cannot anticipate these claims.

Moreover, Wardlaw does not suggest any modification to its valve structure 16 to actually seal the opening in the annulus fibrosus. First, the valve structure 16 is in communication only with the cover 12 that is expanded or inflated within the disc space. Compare FIG. 6B to FIG. 7B; see, col. 9, line 59 – col. 10, line 15. Thus, the fluent material is introduced into the cover in a completely contained or closed system. There is no way for the fluent material to leak from the disc space as the cover is inflated. Since there is no path for the fluent material to leak from the opening in the disc annulus, there is certainly no need to seal that opening.

Furthermore, it is believed that modifying Wardlaw to seal the opening in the disc annulus would inhibit or prevent the inflation of the cover 12 within the disc space. It can be assumed when the disc material has been removed from the disc space that the space is filled with air. As the cover 12 is inflated it necessarily displaces that air. The only escape for this displaced air is back through the opening in the annulus. If that opening is sealed, the displaced air cannot escape. If the air cannot escape, the internal pressure within the disc space must increase as the cover is inflated, which means that the pressure for introducing the fluent material into the cover must increase. Eventually, that pressure will either exceed the ability of the introducing system in Wardlaw to continue to fill the cover, or the pressure will exceed the strength of the disc annulus causing it to rupture. In either case, it is apparent that Wardlaw does not contemplate such a flawed system. Thus, Wardlaw cannot contemplate providing a seal at the annulus opening because to do so would destroy the functionality of the system described in that patent.

It is also noted that Wardlaw specifically contemplates that the opening in the disc annulus remain open during the inflation of the cover 12. In particular, Wardlaw states that, "The hole (or operating port) 58 in the annulus 52 will tend to close as the fibres are stretched, so that the prosthesis 10 which by this time is far greater in size than the operating port 58 is easily retained in position." Col. 10, lines 60-63. In other words, when the cover has been inflated to a size that contacts the interior walls of the annulus, continued inflation of the cover stretches the annulus, which gradually closes the opening. If the opening of the annulus were sealed it could not close as the annulus is stretched.

It can therefore be concluded that the Wardlaw reference fails to disclose sealing the opening in the disc annulus, so it cannot anticipate any of the pending claims. Moreover, Wardlaw provides no motivation to modify the disclosed system to seal the opening in the disc annulus, and more pertinently any such modification would frustrate or destroy the functionality of the Wardlaw system. Thus, the pending claims cannot be rendered obvious in view of Wardlaw, whether taken alone or in an attempted combination with other references.

Additional grounds exist for traversing the rejection of claims 54 and 80. In particular, these claims refer to the seal engaging the annulus fibrosus "adjacent said opening" for sealing the opening. No part of the structure in Wardlaw is disclosed as sealing the annulus adjacent the opening 58. The valve structure 16, interpreted as the seal in the Office Action, is disposed within the opening 58, as clearly shown in FIGS. 6A-8A. A trocar 59 is shown in FIGS. 4A-4B, but this trocar is used to expand the opening/operating port 58, as explained at col. 8, lines 50-53. An external introducer tube 30 is shown in FIGS. 6A-8B, with a port 76 for introducing the fluent material. As shown in more detail in FIG. 5A, this introducer tube 30 is threaded onto the threads 36 of the valve structure 16, as described at col. 7, lines 51-54. There is no suggestion that this introducer tube 30 somehow seals the opening 58. Moreover, for the reasons explained above, the opening 58 must be left unsealed in order for the prosthesis 10 of Wardlaw to work for its intended purpose.

Thus, it can be concluded that Wardlaw cannot anticipate the invention of claims 54 and 80 because it fails to disclose every limitation in those claims, most notably the seal configured to engage the annulus fibrosus "adjacent" the opening in the annulus.

Yet another ground for traverse is present in independent claim 54, as well as in claim 83, which depends from claim 80, and in claims 43-44, which depends from method claim 92. In particular, each of these claims defines a vent in communication with the disc space. In the Office Action it was suggested that the passageway 24 in Wardlaw constituted a "vent". Wardlaw describes the element 24 as being a "longitudinal bore" through the valve structure which is closable by a screw 22. See, col. 7, lines 19-22. As is apparent from FIGS. 2A-2B, the bore 24 is the only passageway through the valve structure 16. It is through this bore that the fluent material passes into

the cover 12, as explained at col. 10, lines 8-13 (the fluent material "flows down the internal passage 40 of the external introducer tube 30 through the bore 24 in the valve structure 16.") The bore 24 cannot be both the passageway for flow of the fluent material and the vent. Moreover, the valve element 18 in the valve structure 16 prevents any backflow of material, which specifically prevents the bore 24 from acting as a vent in any condition.

Again, Wardlaw cannot anticipate independent claim 54 or the dependent claims 43, 44 or 38, because Wardlaw does not disclose a vent as recited in these claims. Moreover, adding a vent to the Wardlaw valve structure 16 would completely frustrate the operation of that structure and prevent inflation of the cover 12. Thus, there is nothing in Wardlaw to suggest modifying the structure disclosed in that reference.

With respect to method claim 92, it can be seen that Wardlaw further fails as an anticipatory reference because it does not disclose every step recited in that claim. In particular, claim 92 defines the step of introducing fluent material into the intradiscal space and "in contiguity with said annulus fibrosus or remaining nucleus pulposus." In contrast, Wardlaw only discloses introducing a fluent material into an inflatable cover. It is the cover in Wardlaw that is "in contiguity" with the disc annulus once the cover is fully inflated, as depicted in FIG. 7B. There is no disclosure in Wardlaw of the fluent material directly contacting the disc annulus or nucleus pulposus, as required by Applicants' claim 92. Moreover, there is no motivation to modify Wardlaw to eliminate the cover 12 and inject the fluent material directly into the disc space. The entire purpose of the Wardlaw disclosure is to provide an inflatable prosthesis that can be filled with hydrogel to provide a disc prosthesis. See, col. 6, line 43 – col. 7, line 17. Any modification to Wardlaw in line with Applicants' claim 92 would render the inflatable cover 12 and the valve structure 16 completely superfluous. Thus, it can be concluded that Wardlaw fails to anticipate claim 92 because it does not disclose every limitation of that claim.

It has been demonstrated that the Wardlaw reference cannot anticipate any of the pending claims because it fails to include every limitation of the independent claims 45, 54, 80 and 92. Moreover, there is no motivation to modify Wardlaw to add these missing elements, particularly since the modifications necessary to meet Applicants' claims would

completely frustrate the function and structure of the system in Wardlaw. Thus, it is believed that these claims 45, 54, 80 and 92 are patentable over the new art of record, along with their respective dependent claims.

It is also believed that the dependent claims are patentable on their own merits. For instance, claim 39 defines the cannula as configured to distract two vertebrae on opposite surfaces of said disc upon placement of said cannula into said opening in the disc annulus. In the Office Action, no reference was made to any structure in Wardlaw that allegedly met this limitation. There is certainly no disclosure of a cannula being used for distraction in Wardlaw, so it cannot anticipate claim 39. A similar argument can be made with respect to claims 52 and 53 which depend from claim 45 and recite a separate distractor, for claim 72, which depends from claim 55 and defines an insertion tip configured to distract, and for claim 85, which depends from claim 80 and adds a distraction tip.

Finally, Applicants have added new claim 97 which depends from method claim 92. This claim adds the limitation that the seal is removed after the fluent material has substantially cured. This element is not disclosed or contemplated by Wardlaw. By necessity, the valve structure 16 in Wardlaw must remain *in situ* once the cover 12 is inflated in order to maintain the seal. Moreover, since the valve structure 16 is resident within the annulus fibrosus, as shown in the figures of Wardlaw, there is no mechanism for somehow severing the valve structure from the cover, even after the fluent material within the inflated cover has cured. It is therefore believed that new claim 97 is patentable over the art of record.

### Conclusion

In view of the foregoing arguments it is believed that the rejection of the pending claims has been traversed. The cited reference of Wardlaw cannot anticipate these claims because it fails to disclose every element recited in the claims. Moreover, any modification to Wardlaw to meet the limitations of the pending claims would completely frustrate the function and structure of the system disclosed in that reference. There is therefore no motivation or suggestion to modify Wardlaw in the manner necessary to

meet the limitations in the pending claims. Therefore, it is requested that these rejections be withdrawn and that action be taken toward a Notice of Allowance.

Respectfully submitted,

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